PUBLIC CITIZEN'S HEALTH RESEARCH GROUP'S COMMENTS ON THE STATUS OF USEFUL WRITTEN PRESCRIPTION DRUG INFORMATION FOR PATIENTS

Docket No. 00N-0352

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and
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The Evaluation of Written Prescription Information Provided in Community Pharmacies: An 8-State Survey (The Survey) is an interim study funded by the Food and Drug Administration (FDA) that was required by the 1996 Action Plan for the Provision of Useful Prescription Medicine Information[1] (Action Plan). The purpose of The Survey was to see how many prescription drug consumers are receiving patient information leaflets (PILs) and whether the unregulated PILs produced by commercial information vendors currently being distributed to consumers meet the Action Plan's definition of useful information. The Survey has failed to provide acceptable information to assess the adequacy of the PILs now being received by consumers and must be promptly redesigned in order to accurately measure the quality of this important information for consumers. By January 1, 2001, 75% of patients who get prescriptions filled are supposed to get patient information leaflets which contain information "consistent with or derived from FDA-approved" labeling for a drug.

Despite the shortcomings of the FDA-funded Survey's design (see below), only 12.5 percent of the PILs distributed with the drug ibuprofen (Motrin) informed

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[1] Action Plan for the Provision of Useful Prescription Medicine Information presented to The Honorable Donna E. Shalala, Secretary of the Department of Health and Human Services by the Steering Committee for the Collaborative Development of a Long-Range Actions Plan for the Provision of Useful Prescription Medicine Information, December 1996.

A Steering Committee met seven times between September 18, 1996 and December 4, 1996 in the Washington DC area in a very contentious debate to develop The Action Plan. Consumer groups advocated for the mandatory distribution by pharmacists of FDA regulated drug information similar to regulations first proposed by the agency in 1979. Consumer groups noted that the private sector had pursued a failed paradigm since the inception of the National Council on Patient Information and Education (NCPIE) in 1982 that has not provided useful information to prescription drug consumers. Entities representing the drug industry, pharmacy and medicine, and commercial information vendors pressed for the *status quo* – voluntary distribution, voluntary quality standards, no oversight, and no FDA involvement.

consumers of the drug's contraindications and what steps to take should the contraindications exist and only 5.3 percent of these PILs included specific precautions, their significance, and how consumers could avoid harm. Despite these worrisome findings, 82.6 percent of these PILs were graded as having high adherence to the Action Plan criterion for being scientifically accurate, that is, containing information "consistent with or derived from FDA-approved" labeling for a drug.

We conducted an informal survey this month of the PILs being distributed for ibuprofen by four Washington DC pharmacies that included the chain pharmacies CVS and RiteAid with a combined total of over 7,900 stores between them. We found that the following critical, potentially life-saving information was not contained in these PILs: (1) that gastrointestinal (GI) perforation, ulceration, and bleeding are the most frequent serious adverse effects associated with the use of ibuprofen; and (2) that GI perforation, ulceration, and bleeding can lead to hospitalization that has resulted in death.

If The Survey's methodology is followed in the subsequent survey that will be used by the Secretary of the Department of Health and Human Services to determine the quality of information contained in commercially prepared PILs, then adherence to the Action Plan guidelines will be overestimated. In our view, the greatest weakness of The Survey's methodology is in not accurately assessing if the information content of commercially prepared PILs is " ... consistent with or derived from FDA-approved labeling ..." for a drug.

Because inadequate access to scientifically accurate drug information is a major cause of the inappropriate use of prescription drugs, resulting in serious personal injury to consumers and related costs to the healthcare system Public Citizen's Health Research Group strongly urges the following:

- The methodology of the next PIL survey must accurately assess the information content of PILs compared to the FDA-approved labeling for a drug.

- The methodology of the next PIL survey must be made available for public comment before the survey is undertaken.

- The evaluation panel must include individuals with a background in drug safety and who are familiar with prescription drug labeling.

- The methodology of the next survey must include a criterion that the standard for useful information is 100 percent adherence to the Action Plan guidelines. Acquiescing to a lower standard would only perpetuate consumers receiving information that is not sufficiently specific and comprehensive to protect themselves.

- We strongly suggest that under the Action Plan's Component B of useful information that other bolded warnings contained in a drug's FDA-approved labeling relevant to consumers be included as a guideline.

- We strongly suggest that the Action Plan guidelines include a guideline that when another drug product is mentioned in a PIL that both generic and a common brand name be listed. The format should be: generic name (common brand name).

The Action Plan resulted from compromise federal legislation (P.L. 104-180)[2] passed after language was inserted in an FDA appropriations bill to prevent the agency from finalizing a 1995 proposed rule[3], a rule similar to the agency's 1979 proposal, to mandate the distribution of useful, scientifically accurate information to consumers with each new prescription by pharmacists. If the Action Plan's quality and quantity goals are not reached by January 1, 2001 the Secretary of the Department of Health and Human Services has the option, after the mandatory period for public comment, to implement the FDA's 1995 proposed rule or another plan to ensure consumer's access to written drug information.

The process of "granting" consumers access to objective useful, scientifically accurate written drug information began in 1979 when the FDA proposed a rule to mandate the distribution of such information with new prescriptions for ten classes of drugs that would have encompassed approximately 350 products. Groups representing the private sector have irresponsibly misplaced their political dogma ahead of the public's health and have prevented consumer's access to useful drug information for over 20 years. Rather than viewing the distribution of useful drug information to consumers as safety and labeling issues, legally under the authority of the FDA, the private sector sees the mandatory distribution of useful information as an unwarranted intrusion on the professional autonomy of physicians and pharmacists and ignores the public need for objective drug information.

THE SURVEY RESULTS

Table 3 of The Survey is noteworthy as it highlights the fact that the unregulated PILs currently being distributed omit substantial risk information that is needed by consumers to make informed decisions to initially use or continue to use a prescription

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[2] Public Law 104-180 (August 6, 1996), *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997.*

[3] Department of Health and Human Services, Food and Drug Administration (FDA). Prescription Drug Product Labeling; Medication Guide Requirements. *Federal Register* 60 (no. 164), August 24, 1995, 44182.

drug. The commercially prepared PILs consistently scored low on The Survey's Criterion 3 (identifies contraindications and what to do if the contraindications are present) and Criterion 4 (includes specific precautions, their significance, and how to avoid harm). For Criterion 3, the percentage of PILs that were classified as having high adherence to the Action Plan guidelines was reported as ibuprofen (12.5%), amoxicillin (31.0%), and paroxetine (21.1%). The percentage of PILs meeting the high adherence classification for Criterion 4 was reported as ibuprofen (5.3%), amoxicillin (73.5%), and paroxetine (15.8%).

In view of the PILs lack of adherence to Criteria 3 and 4 it is remarkable, and contradictory, that the expert panel gave high marks for the commercial PILs on Criterion 9 (information is scientifically accurate and includes a disclaimer). The percentage of PILs classified as attaining high adherence to Criterion 9 was; ibuprofen (82.6%), amoxicillin (89.2%), and paroxetine (61.3%).

The results reported for Criteria 3, 4, and 9 in Table 3 of The Survey suggest that the expert panel has misinterpreted the Action Plan's definition of scientifically accurate. Scientific accuracy, for the purposes of the Action Plan, not only includes that only FDA approved uses appear in PILs, but that risk information that appears in PILs be " ... consistent with or derived from FDA-approved labeling ... ."[4] Also defining useful consumer information is that the information is sufficiently specific and comprehensive. Included in this definition is:

> ... risk information should include enough detail for the consumer to understand the significance of the hazard described; for example, the information should allow consumers to distinguish between a warning about an improper use that could be life-threatening and one that could result in minor discomfort.[5]

An examination of the Patient Information Evaluation Forms (PIEFs) used in The Survey indicate that they do not adequately assess consistency with the FDA-approved professional product labeling (scientific accuracy) of the commercially prepared information being distributed with the three study drugs. Before other factors are considered in the evaluation of the quality of written drug information for consumers, the scientific accuracy of the information must first be adequately assessed. Information that is understandable, legible and readily comprehensible by consumers that lacks scientific accuracy, though communicated well, is not useful information. In fact, it may be misleading and thus potentially dangerous. For example, if consumer information lacks scientifically accurate content about adverse drug

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[4] Action Plan for the Provision of Useful Prescription Medicine Information, December 1996, page 17.

[5] Action Plan for the Provision of Useful Prescription Medicine Information, December 1996, page 19.

reactions or drug interactions and the potential seriousness of these reactions, the information has not been placed in a context that is useful and could affect consumers' decisions to use, or to continue to use, the product.

SURVEY OF PILS FOR IBUPROFEN BEING DISTRIBUTED IN FOUR WASHINGTON DC PHARMACIES

Table 4 of The Survey is an analysis of the percentage of PILs with partial or full adherence to drug-specific sub-criteria for the PILs distributed with the study drug ibuprofen. Criterion 5 of the PIEF for the ibuprofen PILs is "Information includes enough detail for proper monitoring and interpretation of serious or frequently occurring adverse reactions." The first sub-criterion evaluated under Criterion 5 is if the ibuprofen PILs are sufficiently specific and comprehensive regarding the risk of gastrointestinal (GI) toxicity with ibuprofen:

> stop taking and call provider immediately if: severe GI effects occur, for ex., bleeding, ulceration, black or bloody stools; effects may result in hospitalization, may be fatal

The Survey's expert panel found that 95.5 percent of PILs distributed with ibuprofen partially or fully adhered to the above sub-criterion. This result points to a major weakness in The Survey's methodology. If one of the elements assessed by this criterion is missing from a PIL, the PIL can not be classified as adhering to the Action Plan guideline for sufficiently specific and comprehensive information and thus cannot count as useful information. The national expert panel's scoring partial adherence is therefore invalid in assessing if an ibuprofen PIL is sufficiently specific and comprehensive to be considered to be useful information.

Our skepticism of this result led us to survey the ibuprofen PILs being distributed by a convenience sample of four pharmacies in Washington DC. Using the FDA-approved professional product labeling for ibuprofen and the Action Plan guideline that useful information is sufficiently specific and comprehensive for consumers we evaluated the content of the PILs obtained from the four Washington DC pharmacies for the four following elements:

7. GI perforation, ulceration, and bleeding are the most frequent serious adverse effects associated with the use of ibuprofen.

8. GI perforation, ulceration, and bleeding can lead to hospitalization that has resulted in death.

9. Specifically identifies the symptoms of ibuprofen induced GI toxicity: severe abdominal or stomach pain, cramping, or burning, severe and continuing nausea, heartburn or indigestion, bloody or black, tarry stools, vomiting blood or

matter that looks like coffee grounds, or spitting up blood.

10. If the symptoms of GI toxicity develop stop the drug at once and contact your doctor immediately.

Our results appear in Table 1 below. The name of the pharmacy, the date we obtained an ibuprofen PIL, and the name of the commercial information vendor, if known, is listed in column one. Column two lists which of the above four elements were missing from the PILs we obtained.

The PILs we obtained from the four pharmacies appear as Appendices 1 through 4 at the end of these comments.

None of the four PILs informed consumers that GI toxicity is the most serious adverse effect associated with the use of ibuprofen and that GI toxicity can lead to hospitalization and death. This type of risk information is essential for consumers to make informed decisions about their drug therapy.

Table 1 - Results of an Informal Survey of the Information Content for GI Toxicity Information Contained in PILs being Distributed by Four Pharmacies for Ibuprofen.

Pharmacy/Date Obtained/Commercial Information Vendor if Known	Elements Omitted in the GI Toxicity Warning for Ibuprofen PILs
Safeway Pharmacy, Arlington VA/ February 21, 2000/ Vendor Unknown	1. GI perforation, ulceration, and bleeding are the most frequent serious adverse effects associated with the use of ibuprofen. 2. GI perforation, ulceration, and bleeding can lead to hospitalization that has resulted in death.
Tschiffely Pharmacy, 1330 Connecticut Ave., NW, Washington DC/ February 21, 2000/ First DataBank, Inc., Ver. 99.4	1. GI perforation, ulceration, and bleeding are the most frequent serious adverse effects associated with the use of ibuprofen. 2. GI perforation, ulceration, and bleeding can lead to hospitalization that has resulted in death.

Table 1 - Results of an Informal Survey of the Information Content for GI Toxicity Information Contained in PILs being Distributed by Four Pharmacies for Ibuprofen.	
Pharmacy/Date Obtained/Commercial Information Vendor if Known	Elements Omitted in the GI Toxicity Warning for Ibuprofen PILs
CVS Pharmacy, DuPont Circle, Washington DC/ February 22, 2000/ Vendor Unknown	1. GI perforation, ulceration, and bleeding are the most frequent serious adverse effects associated with the use of ibuprofen. 2. GI perforation, ulceration, and bleeding can lead to hospitalization that has resulted in death.
Rite Aid Pharmacy, Connecticut Ave., NW, Washington DC/ February 22, 2000/ Vendor Unknown	1. GI perforation, ulceration, and bleeding are the most frequent serious adverse effects associated with the use of ibuprofen. 2. GI perforation, ulceration, and bleeding can lead to hospitalization that has resulted in death.

THE ADEQUACY OF THE PIEFs USED IN THE SURVEY

The PIEFs developed by the national expert panel, in a number of instances, fail to adequately assess the information content of the PILs in comparison to the FDA-approved professional product labeling for the three study drugs ibuprofen, amoxicillin, and paroxetine. The Action Plan lists 11 components of useful written drug information for consumers. These are discussed on page 20 of the Action Plan and are meant as a "floor" for defining written prescription drug information as sufficiently specific and comprehensive for consumers.

The three tables below, one for each study drug, summarize information required in the Action Plan that was incorrectly assessed or omitted in the PIEFs developed by the national expert panel. These tables were constructed by first preparing additional tables for each study drug and categorizing the information contained in the drug's approved product labeling according to the 11 components of useful information defined in the Action Plan. Only the Action Plan components where information was incorrectly assessed or omitted from evaluation by a PIEF are listed in the following tables along with the information from the drug's FDA-approved labeling that should have been assessed by the PIEF.

The tables constructed from the FDA-approved product labeling for the three study drugs are listed as Appendices 5, 6 and 7 at the end of these comments.

IBUPROFEN[6]

The PIEF used to evaluate the ibuprofen PILs failed to assess an off-label use for the drug. Use of the drug in pediatric populations was not assessed, a serious contraindication was omitted, as were important precautions, including drug interactions, and frequently occurring adverse drug reactions.

Table 2 - Ibuprofen, Patient Information Evaluation Form (PIEF) Deviations from the Action Plan Guidelines for the Components of Useful Information	
Component C – A section that identifies a medicine's indication for use, including pediatric indications if any.	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
" ... also reduces fever"	fever reduction is not listed as an indication
Omitted	"Controlled clinical trials to establish the safety and effectiveness of MOTRIN in children have not been conducted."
Component D – Information on the circumstances under which the medicine should not be used for its labeled indication (i.e., its contraindications).	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omits the risk of the drug in those with the syndrome of nasal polyps.	CONTRAINDICATIONS " ... those with syndrome of nasal polyps ... ."
Component E – If applicable, a statement or statements of precautions the consumer should take to ensure proper use of the medicine.	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omitted	"Blurred and/or diminished vision, scotomata, and/or changes in color vision have been reported. If a patient develops such complaints while receiving MOTRIN Tablets, the drug should be discontinued, and the patient should have an ophthalmologic examination which includes central visual fields and color vision testing."
Omitted	"Aseptic meningitis with fever and coma has been observed on rare occasions in patients on ibuprofen therapy."

[6] Professional Product Labeling for Motrin (ibuprofen), Pharmacia & Upjohn. Revised April 1997.

Omitted	DRUG INTERACTION: METHOTREXATE "Ibuprofen, as well as other nonsteroidal anti-inflammatory drugs, probably reduces the tubular secretion of methotrexate based on *in-vitro* studies in rabbit kidney slices. This may indicate that ibuprofen could enhance the toxicity of methotrexate. Caution should be used if MOTRIN is administered concomitantly with methotrexate."
Omitted	DRUG INTERACTION: FUROSEMIDE "Clinical studies, as well as random observations, have shown that ibuprofen can reduce the natriuretic effect of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with ibuprofen, the patient should be observed for signs of renal failure, as well as to assure diuretic efficacy."
Omitted	DRUG INTERACTION: LITHIUM "Ibuprofen produced an elevation of plasma lithium levels and a reduction in renal lithium clearance in a study of eleven normal volunteers. ... Thus, when ibuprofen and lithium are administered concurrently, subjects should be observed carefully for signs of lithium toxicity."

Component F – A statement of the symptoms that indicate possible adverse reactions from the use of the medicine that are serious or occur frequently (frequent adverse reactions are defined as those occurring in at least 1/100 patients 21 CFR § 201.57(g)(2)). The adverse reactions below are listed in the ibuprofen professional product labeling as occurring at an incidence of greater than 1 percent.	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omitted	tinnitus (ringing in the ears)
Omitted	decreased appetite

AMOXICILLIN

The professional product labeling for the study drug amoxicillin[7] carries two bolded warnings. The first regarding, " ... SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTIC) REACTIONS ... " and the second that "**Pseudomembranous colitis** [inflammation of the intestines] **has been reported with nearly all antibacterial agents, including amoxicillin, and may range in severity**

[7] Professional Product Labeling for Amoxil (amoxicillin), SmithKline Beechan Pharmaceuticals. Date of issuance July 1999.

from mild to life-threatening."

The PIEF for the amoxicillin PILs does evaluate if consumers are informed to stop taking the drug and call the doctor immediately if severe skin rash, hives, itching, or difficulty breathing or swallowing occur (these are symptoms of a potentially life-threatening allergic reaction) or if severe diarrhea or cramps are experienced (these are the symptoms of a potentially life-threatening inflammation of the intestine). However, the PIEF does not evaluate if consumers are informed that these are symptoms of life-threatening adverse drug reactions.

The PIEF developed by the national expert panel for amoxicillin omitted the evaluation of two important precautions and three potentially serious adverse drug reactions.

Table 3 - Amoxicillin, Patient Information Evaluation Form (PIEF) Deviations from the Action Plan Guidelines for the Components of Useful Information	
Component E – If applicable, a statement or statements of precautions the consumer should take to ensure proper use of the medicine.	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omitted	Phenylketonurics: 200 mg and 400 mg chewable tablets
Omitted	DRUG INTERACTION: Probenecid may result in increased and prolonged blood levels of amoxicillin.
Component F – A statement of the symptoms that indicate possible adverse reactions from the use of the medicine that are serious or occur frequently.	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omitted	Liver: cholestatic jaundice, hepatic cholestatis and acute cytolytic hepatitis
Omitted	Hemic and Lymphatic Systems: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis
Omitted	Central Nervous System: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and/or dizziness

PAROXITENE

The professional product labeling for paroxetine carries a bold warning concerning the possibility of serious, sometimes fatal reactions when a selective serotonin reuptake inhibitor (SSRI) antidepressant similar to paroxetine is taken in combination with monoamine oxidase inhibitors (MAOIs) or within 14 days of discontinuing treatment with a MAOI.[8] The Action Plan's components of useful information contain the guideline:

> ... a statement of precaution regarding any circumstances in which the use of the medicine could lead to serious injury or death.[9]

The PIEF developed for the Paroxetine PIL does not evaluate if the life-threatening nature of the possible interaction between paroxetine and MAOIs is contained in the information being distributed to consumers. Omission of this information does not " ... allow consumers to distinguish between a warning about an improper use that could be life-threatening and one that could result in minor discomfort."

The expert panel's PIEF used to evaluate paroxetine PILs omitted evaluation of one FDA-approved use for the drug and one contraindication for using the drug. In addition, this PIEF did not evaluate the content of paroxetine PILs for 14 precautions, including drug interactions, and omitted evaluating 25 frequently occurring adverse drug reactions.

Table 4 - Paroxitene, Patient Information Evaluation Form (PIEF) Deviations from the Action Plan Guidelines for the Components of Useful Information	
Component C - A section that identifies a medicine's indication for use, including pediatric indications if any.	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omitted	Social anxiety disorder
Component D - Information on the circumstances under which the medicine should not be used for its labeled indication (i.e., its contraindications).	

[8] Professional product labeling for paroxetine (Paxil). Physicians' Desk Reference 54th ed. Montvale NJ: Medical Economics Company, Inc., 2000.

[9] Action Plan for the Provision of Useful Prescription Medicine Information, December 1996, page 21.

PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omitted	"Hypersensitivity to paroxetine or any of the inactive ingredients in Paxil."
Component E – If applicable, a statement or statements of precautions the consumer should take to ensure proper use of the medicine.	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omitted	Activation of Mania/Hypomania
Omitted	History of Seizures
Omitted	History of Suicide
Omitted	Hyponatremia (low sodium levels)
Omitted	Abnormal Bleeding
Omitted	Use in Patients with Concomitant Illness: Paxil has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from clinical studies during the product's premarket testing.
Omitted	DRUG INTERACTION: Tryptophan
Omitted	DRUG INTERACTION: Warfarin
Omitted	DRUG INTERACTION: Sumatriptan
Omitted	DRUG INTERACTION: Tricyclic Antidepressants
Omitted	DRUG INTERACTION: Lithium
Omitted	DRUG INTERACTION: Digoxin
Omitted	DRUG INTERACTION: Procyclidine
Omitted	DRUG INTERACTION: Theophylline
Component F – A statement of the symptoms that indicate possible adverse reactions from the use of the medicine that are serious or occur frequently (frequent adverse reactions are defined as those occurring in at least 1/100 patients 21 CFR § 201.57(g)(2)). The adverse reactions below are listed in the paroxetine professional product labeling as occurring at an incidence of greater than 1 percent in patients treated for depression.	
PIEF deviation from the Action Plan Guidelines	FDA-Approved Labeling
Omitted	Headache

Omitted	Palpitation
Omitted	Vasodilation
Omitted	Sweating
Omitted	Rash
Omitted	Constipation
Omitted	Diarrhea
Omitted	Decreased appetite
Omitted	Flatulence
Omitted	Oropharynx disorder
Omitted	Dyspepsia
Omitted	Myopathy
Omitted	Myalgia
Omitted	Mysasthenia
Omitted	Somnolence
Omitted	Dizziness
Omitted	Insomia
Omitted	Tremor
Omitted	Nervousness
Omitted	Paresthesia
Omitted	Drugged feeling
Omitted	Confusion
Omitted	Yawn
Omitted	Blurred vision
Omitted	Taste perversion

APPENDIX 1 - OBTAINED FROM SAFEWAY PHARMACY

BRAND NAME: MOTRIN 600MG TAB PHAR
GENERIC NAME: IBUPROFEN (eye-byoo-PROE-fen)

COMMON USES: This medicine is a nonsteroidal anti-inflammatory drug (NSAID) used to relieve the symptoms of arthritis. It is also used to relieve pain and to treat other conditions as determined by your doctor.

HOW TO USE THIS MEDICINE: Follow the directions for using this medicine provided by your doctor. TAKE THIS MEDICINE with food and a glass of water or with milk. STORE THIS MEDICINE at room temperature, away from heat and light. IF YOU MISS A DOSE OF THIS MEDICINE, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

CAUTIONS: DO NOT TAKE THIS MEDICINE if you ever had any unusual or allergic reaction to aspirin, ibuprofen, naproxen, or any other medicine used to treat pain, fever, swelling, or arthritis. DO NOT DRIVE, OPERATE MACHINERY, OR DO ANYTHING ELSE THAT COULD BE DANGEROUS until you know how you react to this medicine. Using this medicine alone, with other medicines, or with alcohol may lessen your ability to drive or to perform other potentially dangerous tasks. ALCOHOL WARNING: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take this medicine or other pain relievers/fever reducers. This medicine may cause stomach bleeding. BEFORE YOU BEGIN TAKING ANY NEW MEDICINE, either prescription or over-the-counter, check with your doctor or pharmacist. This includes any medicine which contains aspirin or other non-prescription pain relievers.

POSSIBLE SIDE EFFECTS: SIDE EFFECTS, that may go away during treatment, include nausea, vomiting, diarrhea, gas, constipation, indigestion, stomach cramps, dizziness, lightheadedness, drowsiness, or headache. If they continue or are bothersome, check with your doctor. CHECK WITH YOUR DOCTOR AS SOON AS POSSIBLE if you experience swelling of hands or ankles, ringing in ears, rash, itching, vomiting material that looks like coffee grounds, blood in stool or vomit, or stomach

pain. CONTACT YOUR DOCTOR IMMEDIATELY if you experience swelling of hands, face, lips, eyes, throat, or tongue; difficulty swallowing or breathing; or hoarseness. If you notice other effects not listed above, contact your doctor, nurse, or pharmacist.

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you are taking or would like more information, check with your doctor, pharmacist, or nurse.

APPENDIX 2

TSCHIFFELY PHARMACY-DUPONT CIRCLE 1330 CONNECTICUT AVE NW WASHINGTON, DC 20036, TELE:202-331-7176 FAX: 202-331-5808
HOURS:MONDAY-FRIDAY 8:30AM-6:30PM; SAT.10-4PM CLOSED-SUNDAY

Patient: DF Date: 02/21/00
Rx Num: 0 Page 1
Drug: IBUPROFEN TAB 400MG
Dosage:

GENERIC NAME: IBUPROFEN (eye-byoo-PROE-fen),

COMMON USES: This medicine is a nonsteroidal anti-inflammatory drug (NSAID) used to relieve the symptoms of arthritis. It is also used to relieve pain and to treat other conditions as determined by your doctor.

BEFORE USING THIS MEDICINE: Some medicines or medical conditions may interact with this medicine. INFORM YOUR DOCTOR OR PHARMACIST of all prescription and over-the-counter medicine that you are taking. DO NOT TAKE THIS MEDICINE if you are also taking heparins or tacrolimus. ADDITIONAL MONITORING OF YOUR DOSE OR CONDITION may be needed if you are taking aminoglycoside antibiotics, anticoagulants, cyclosporine, lithium, or methotrexate. Inform your doctor of any other medical conditions, allergies, pregnancy, or breast-feeding. Contact your doctor or pharmacist if you have any questions or concerns about taking this medicine.

HOW TO USE THIS MEDICINE: Follow the directions for using this medicine provided by your doctor. TAKE THIS MEDICINE with food and a glass of water or with milk. STORE THIS MEDICINE at room temperature, away from heat and light. IF YOU MISS A DOSE OF THIS MEDICINE, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

CAUTIONS: DO NOT TAKE THIS MEDICINE if you ever had any unusual or allergic reaction to aspirin, ibuprofen, naproxen, or any other medicine used to treat pain, fever, swelling, or arthritis. DO NOT DRIVE, OPERATE MACHINERY, OR DO ANYTHING ELSE THAT COULD BE DANGEROUS until you know how you react to this medicine. Using this medicine alone, with other medicines, or with alcohol may lessen your ability to drive or to perform other potentially dangerous tasks. ALCOHOL WARNING: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take this medicine or other pain relievers/fever reducers. This medicine may cause stomach bleeding. BEFORE YOU BEGIN TAKING ANY NEW MEDICINE, either prescription or over-the-counter, check with your doctor or pharmacist. This includes any medicine which contains aspirin or other non-prescription pain relievers.

POSSIBLE SIDE EFFECTS: SIDE EFFECTS, that may go away during treatment, include nausea, vomiting, diarrhea, gas, constipation, indigestion, stomach cramps, dizziness, lightheadedness, drowsiness, or headache. If they continue or are bothersome, check with your doctor. CHECK WITH YOUR DOCTOR AS SOON AS POSSIBLE if you experience (continued)swelling of hands or ankles, ringing in ears, rash, itching, vomiting material that looks like coffee grounds, blood in stool or vomit, or stomach pain. CONTACT YOUR DOCTOR IMMEDIATELY if you experience swelling of hands, face, lips, eyes, throat, or tongue; difficulty swallowing or breathing; or hoarseness. If you notice other effects not listed above, contact your doctor, nurse, or pharmacist.

OVERDOSE: IF OVERDOSE IS SUSPECTED, contact your local poison control center or emergency room immediately.

ADDITIONAL INFORMATION: DO NOT SHARE THIS MEDICINE with others for whom it was not prescribed. DO NOT USE THIS MEDICINE for other health conditions. KEEP THIS MEDICINE out of the reach of children. IF USING THIS MEDICINE FOR AN EXTENDED PERIOD OF TIME, obtain refills before your supply runs out.

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you. are taking or would like more information, check with your doctor, pharmacist, or nurse.

APPENDIX 3 - OBTAINED FROM CVS PHARMACY

NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID) - ORAL

USES: This medication relieves pain and reduces inflammation. It is used to treat headaches, muscle aches, dental pain, menstrual cramps, athletic injuries, and arthritis. This medication can also reduce fever.

HOW TO TAKE THIS MEDICATION: If stomach upset occurs while taking this medication, take it with food, milk or an antacid. This medication is most effective in relieving menstrual pain if taken at the earliest sign of pain.
In arthritis, it may take up to two weeks before the full effects of this medication are noted. For best results this should be taken regularly, as directed by your doctor.

SIDE EFFECTS: Stomach upset is the most common side effect. If this persists or becomes severe, notify your doctor.
Inform your doctor if you develop persistent stomach pain, presence of black or bloody stools, skin rash, itching, edema (swelling of the feet or hands), change in urine color or vision changes while taking this medication.
This drug may cause dizziness, drowsiness or blurred vision. It may rarely cause ringing in the ears or loss of hearing.
Infrequently, this medication may increase the skin's sensitivity to sunlight. If this happens to you, avoid prolonged sun exposure, wear protective clothing and use a sunscreen. Avoid sunlamps.
In the unlikely event you have an allergic reaction to this drug, seek immediate medical attention. Symptoms of an allergic reaction include rash, itching, swelling, dizziness or breathing trouble.
If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS: Tell your doctor your medical history especially of liver or kidney disease, blood disorders, ulcers, heart disease, alcohol use, high blood pressure, eye disease and of any allergies.
Use caution when performing tasks requiring alertness. Limit alcohol intake as it may intensify the drowsiness effect of this medication.
This medicine may cause stomach bleeding. Daily use of alcohol, especially when combined with this medicine, may increase your risk for stomach bleeding. Check with your doctor or pharmacist for more information.
Caution is advised when this drug is used in the elderly, since this group is more sensitive to drug side effects.
This medication should be used during pregnancy only if clearly needed. Discuss the risks and benefits with your doctor. Use of this drug during the last 6 months of pregnancy is not recommended.
This drug may be excreted into breast milk. Consult your doctor before breast-feeding.
DRUG INTERACTIONS: Tell your doctor of all prescription and nonprescription drugs you may use, especially of warfarin, other arthritis medication (including aspirin or methotrexate), "water pills", lithium and of ulcer medication.
Do not take aspirin without consulting your doctor. Check the ingredients of any nonprescription medication you may be taking since many cough-and-cold formulas contain aspirin.
Do not start or stop any medicine without doctor or pharmacist approval.

NOTES: Do not share this medication with others.

MISSED DOSE: If you miss a dose, take as soon as remembered; do not take if it is almost time for the next dose, instead, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

STORAGE: Store at room temperature away from moisture and sunlight. Do not store in the bathroom.

QUESTIONS? ASK YOUR RITE AID PHARMACIST.

RITE AID

RX: IBUPROFEN 800MG TABLET
Directions: TAKE 1 TABLET 3 TIMES A DAY

IMPORTANT NOTE: THE FOLLOWING INFORMATION IS INTENDED TO SUPPLEMENT, NOT SUBSTITUTE FOR, THE EXPERTISE AND JUDGMENT OF YOUR PHYSICIAN, PHARMACIST OR OTHER HEALTHCARE PROFESSIONAL.

IT SHOULD NOT BE CONSTRUED TO INDICATE THAT USE OF THE DRUG IS SAFE, APPROPRIATE, OR EFFECTIVE FOR YOU.

CONSULT YOUR HEALTHCARE PROFESSIONAL BEFORE USING THIS DRUG.

NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID) - ORAL

USES: This medication relieves pain and reduces inflammation. It is used to treat headaches, muscle aches, dental pain, menstrual cramps, athletic injuries, and arthritis. This medication can also reduce fever.

HOW TO TAKE THIS MEDICATION: If stomach upset occurs while taking this medication, take it with food, milk or an antacid. This medication is most effective in relieving menstrual pain if taken at the earliest sign of pain. In arthritis, it may take up to two weeks before the full effects of this medication are noted. For best results this should be taken regularly, as directed by your doctor.

SIDE EFFECTS: Stomach upset is the most common side effect. If this persists or becomes severe, notify your doctor. Inform your doctor if you develop persistent stomach pain, presence of black or bloody stools, skin rash, itching, edema (swelling of the feet or hands), change in urine color or vision changes while taking this medication. This drug may cause dizziness, drowsiness or blurred vision. It may rarely cause ringing in the ears or loss of hearing. Infrequently, this medication may increase the skin's sensitivity to sunlight. If this happens to you, avoid prolonged sun exposure, wear protective clothing and use a sunscreen. Avoid sunlamps. In the unlikely event you have an allergic reaction to this drug, seek immediate medical attention. Symptoms of an allergic reaction include rash, itching, swelling, dizziness or breathing trouble. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS: Tell your doctor your medical history especially of liver or kidney disease, blood disorders, ulcers, heart disease, alcohol use, high blood pressure, eye disease and of any allergies. Use caution when performing tasks requiring alertness. Limit alcohol intake as it may intensify the drowsiness effect of this medication. This medicine may cause stomach bleeding. Daily use of alcohol, especially when combined with this medicine, may increase your risk for stomach bleeding. Check with your doctor or pharmacist for more information. Caution is advised when this drug is used in the elderly, since this group is more sensitive to drug side effects. This medication should be used during pregnancy only if clearly needed. Discuss the risks and benefits with your doctor. Use of this drug during the last 6 months of pregnancy is not recommended. This drug may be excreted into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: Tell your doctor of all prescription and nonprescription drugs you may use, especially of warfarin, other arthritis medication (including aspirin or methotrexate), "water pills", lithium and of ulcer medication. Do not take aspirin without consulting your doctor. Check the ingredients of any nonprescription medication you may be taking since many cough-and-cold formulas contain aspirin. Do not start or stop any medicine without doctor or pharmacist approval.

NOTES: Do not share this medication with others.

MISSED DOSE: If you miss a dose, take as soon as remembered; do not take if it is almost time for the next dose, instead, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

STORAGE: Store at room temperature away from moisture and sunlight. Do not store in the bathroom.

The information in this leaflet may be used as an educational aid. This information does not cover all possible uses, actions, precautions, side effects, or interactions of this medicine. This information is not intended as medical advice for individual

Rite ADVICE℠

ORDER NO. 460303

SHEET 1 of 2

APPENDIX 4

APPENDIX 5 - COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR IBUPROFEN		
A. NAME	Yes	No
Established Name		
Brand Name		
Phonetic Spelling		
B. BLACK BOX WARNING (If Applicable)		
Other Bolded Warnings: Risk of GI ulceration, bleeding and perforation with nonsteroidal anti-inflammatory therapy.		
C. INDICATIONS FOR USE	Yes	No
Rheumatoid Arthritis		
Osteoarthritis		
Mild to Moderate Pain		
Primary Dysmenorrhea		
Pediatric Use: Controlled clinical trials to establish the safety and effectiveness of MOTRIN in children have not been conducted.		
Off-Label Uses		
D. CONTRAINDICATIONS	Yes	No
Hypersensitivity to Ibuprofen		
Syndrome of Nasal Polyps		
History of Angioedema and Bronchospastic Reactions to Aspirin or other Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
E. PRECAUTIONS	Yes	No
WARNINGS: Risk of GI ulceration, bleeding, and perforation that may result in hospitalization and even fatal outcomes.		
Signs and Symptoms of Serious GI Toxicity		
Steps to take if the signs and symptoms of serious GI toxicity occur		
Blurred and/or diminished vision, scotoma, and/or changes in color vision. If such effects occur the drug should be stopped.		
History of Cardiac Decompensation		
History of Hypertension		

APPENDIX 5 – COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR IBUPROFEN		
Intrinsic Coagulation Defects		
Anticoagulant Therapy		
Risk of Liver Toxicity. Jaundice and fatal hepatitis		
Signs and symptoms of liver toxicity		
Steps to take if the signs and symptoms of liver toxicity occur		
Aseptic Meningitis with fever and coma		
Decreased Hemoglobin Level		
Renal Effects. Greatest risk those with impaired kidney function, heart failure, liver dysfunction, those taking diuretics, and the elderly.		
Drug Interaction: Warfarin		
Drug Interaction: Aspirin		
Drug Interaction: Methotrexate		
Drug Interaction: Lithium		
Use in pregnancy: Administration of MOTRIN during pregnancy		
Use when breast feeding: MOTRIN is not recommended for use in nursing mothers		
F. POSSIBLE ADVERSE REACTIONS (frequent > 1%)	Yes	No
Gastrointestinal: Nausea, epigastric pain, heartburn, diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of GI tract (bloating and flatulence)		
Central Nervous System: Dizziness, headache, nervousness		
Dermatologic: Rash		
Tinnitus (ringing in the ears)		
Decreased Appetite		
Cardiovascular: Edema, fluid retention		
G. TOLERANCE/DEPENDENCE (if applicable)		
H. PROPER USE	Yes	No
1. A statement stressing the importance of adhering to the dosing instructions.		
2. A statement of what the patient should do if he or she misses taking scheduled doses.		

APPENDIX 5 – COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR IBUPROFEN		
3. A statement describing any special instructions on how to administer the medicine.		
4. A statement about what the patient should do in case of overdose of the medicine.		
I. PROPER STORAGE INSTRUCTIONS		
J. GENERAL INFORMATION	Yes	No
1. A statement encouraging discussion with a health care professional about the prescription medicine.		
2. A statement that the medicine should only be used by the patient for whom it is prescribed and is not to be given to other persons.		
3. The name of the publisher of the information.		
4. The date of publication or most recent revision or review for adequacy and accuracy of content.		
K. A DISCLAIMER STATEMENT CONTAINING THE FOLLOWING CONCEPTS	Yes	No
1. The materials are summaries and do not contain all possible information about the medicine.		
2. The health care professional who has prescribed the medicine has more information.		
3. The health care professional's information addresses both medicine and the patient's specific health needs.		
4. the health care professional can provide and answer questions about the information in the professional labeling.		

APPENDIX 6 - COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR AMOXICILLIN		
A. NAME	Yes	No
Established Name		
Brand Name		
Phonetic Spelling		
B. BLACK BOX WARNING (If Applicable)		
Other Bolded Warnings: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions:		
Other Bolded Warnings: Potentially Fatal Pseudomembranous colitis		
C. INDICATIONS FOR USE	Yes	No
Infections of the ear, nose, and throat		
Infections of the genitourinary tract		
Infections of the skin and skin structure		
Infections of the lower respiratory tract		
Acute uncomplicated gonorrhea		
H. pylori eradication to reduce the risk of duodenal ulcer recurrence		
D. CONTRAINDICATIONS	Yes	No
A history of allergic reaction to any of the penicillins		
E. PRECAUTIONS	Yes	No
Phenylketonurics: 200 mg and 400 mg chewable tablets contain phenylalanine.		
High urine concentrations of ampicillin may result in false-positive reactions when testing for the presence of glucose in urine using Clinitest, Benedict's Solution or Fehling's Solution.		
Drug Interaction: Probenecid may result in increased and prolonged blood levels of amoxicillin.		
Use in pregnancy: This drug should be used during pregnancy only if clearly indicated.		
Use when breast feeding: Caution should be exercised when amoxicillin is administered to a nursing woman.		
F. POSSIBLE ADVERSE REACTIONS	Yes	No
Gastrointestinal: nausea, vomiting, diarrhea, hemorrhagic/pseudomembranous colitis.		

APPENDIX 6 – COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR AMOXICILLIN		
Hypersensitivity Reactions: Various rashes		
Liver: cholestatic jaundice, hepatic cholestatis and acute cytolytic hepatitis		
Hemic and Lymphatic Systems: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis		
Central Nervous System: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and/or dizziness		
G. TOLERANCE/DEPENDENCE (if applicable)		
H. PROPER USE	Yes	No
1. A statement stressing the importance of adhering to the dosing instructions.		
2. A statement of what the patient should do if he or she misses taking scheduled doses.		
3. A statement describing any special instructions on how to administer the medicine.		
4. A statement about what the patient should do in case of overdose of the medicine.		
I. PROPER STORAGE INSTRUCTIONS		
J. GENERAL INFORMATION	Yes	No
1. A statement encouraging discussion with a health care professional about the prescription medicine.		
2. A statement that the medicine should only be used by the patient for whom it is prescribed and is not to be given to other persons.		
3. The name of the publisher of the information.		
4. The date of publication or most recent revision or review for adequacy and accuracy of content.		
K. A DISCLAIMER STATEMENT CONTAINING THE FOLLOWING CONCEPTS	Yes	No
1. The materials are summaries and do not contain all possible information about the medicine.		
2. The health care professional who has prescribed the medicine has more information.		
3. The health care professional's information addresses both medicine and the patient's specific health needs.		

APPENDIX 6 – COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR AMOXICILLIN		
4. The health care professional can provide and answer questions about the information in the professional labeling.		

APPENDIX 7 – COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR PAROXETINE		
A. NAME	Yes	No
Established Name		
Brand Name		
Phonetic Spelling		
B. BLACK BOX WARNING (if applicable)		
Other Bolded Warnings: Potential Interaction with Monoamine Oxidase Inhibitors (MAOIs) that are serious and sometimes fatal		
C. INDICATIONS FOR USE	Yes	No
Depression		
Obsessive Compulsive Disorder		
Panic Disorder		
Social Anxiety Disorder		
Pediatric use: Safety and effectiveness in the pediatric population have not been established.		
D. CONTRAINDICATIONS	Yes	No
Hypersensitivity to paroxetine or any of the inactive ingredients in Paxil		
E. PRECAUTIONS	Yes	No
Activation of Mania/Hypomania		
Seizures		
Suicide		
Hyponatremia (low sodium levels)		
Abnormal Bleeding		
Use in Patients with Concomitant Illness: Paxil has not been evaluated or used to any appreciable extent in patients with a recent history of myocardial infarction or unstable heart disease. Patients with these diagnoses were excluded from clinical studies during the product's premarket testing.		
Drug Interaction: Tryptophan		
Drug Interaction: Warfarin		
Drug Interaction: Sumatriptan		

APPENDIX 7 - COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR PAROXETINE		
Drug Interaction: Tricyclic Antidepressants		
Drug Interaction: Alcohol		
Drug Interaction: Lithium		
Drug Interaction: Digoxin		
Drug Interaction: Procyclidine		
Drug Interaction: Theophylline		
Use during pregnancy: This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.		
Use when breast feeding: Caution should be exercised when Paxil is administered to a nursing woman.		
F. POSSIBLE ADVERSE REACTIONS - (frequent > 1%) WHEN USED IN DEPRESSION	Yes	No
Headache		
Asthenia		
Palpitation		
Vasodilation		
Sweating		
Rash		
Nausea		
Dry mouth		
Constipation		
Diarrhea		
Decreased appetite		
Flatulence		
Oropharynx disorder		
Dyspepsia		
Myopathy		
Myalgia		
Myasthenia		

APPENDIX 7 – COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR PAROXETINE		
Somnolence		
Dizziness		
Insomia		
Tremor		
Nervousness		
Anxiety		
Paresthesia		
Libido decreased		
Drugged feeling		
Confusion		
Yawn		
Blurred vision		
Taste perversion		
Ejaculatory disturbance		
Other male genital disorders		
Urinary frequency		
Urination disorder		
Female genital disorder		
G. TOLERANCE/DEPENDENCE (if applicable)		
H. PROPER USE	Yes	No
1. A statement stressing the importance of adhering to the dosing instructions.		
2. A statement of what the patient should do if he or she misses taking scheduled doses.		
3. A statement describing any special instructions on how to administer the medicine.		
4. A statement about what the patient should do in case of overdose of the medicine.		
I. PROPER STORAGE INSTRUCTIONS		

APPENDIX 7 – COMPONENTS OF USEFUL INFORMATION CONSISTENT WITH OR DERIVED FROM THE FDA-APPROVED LABELING FOR PAROXETINE		
J. GENERAL INFORMATION	Yes	No
1. A statement encouraging discussion with a health care professional about the prescription medicine.		
2. A statement that the medicine should only be used by the patient for whom it is prescribed and is not to be given to other persons.		
3. The name of the publisher of the information.		
4. The date of publication or most recent revision or review for adequacy and accuracy of content.		
K. A DISCLAIMER STATEMENT CONTAINING THE FOLLOWING CONCEPTS	Yes	No
1. The materials are summaries and do not contain all possible information about the medicine.		
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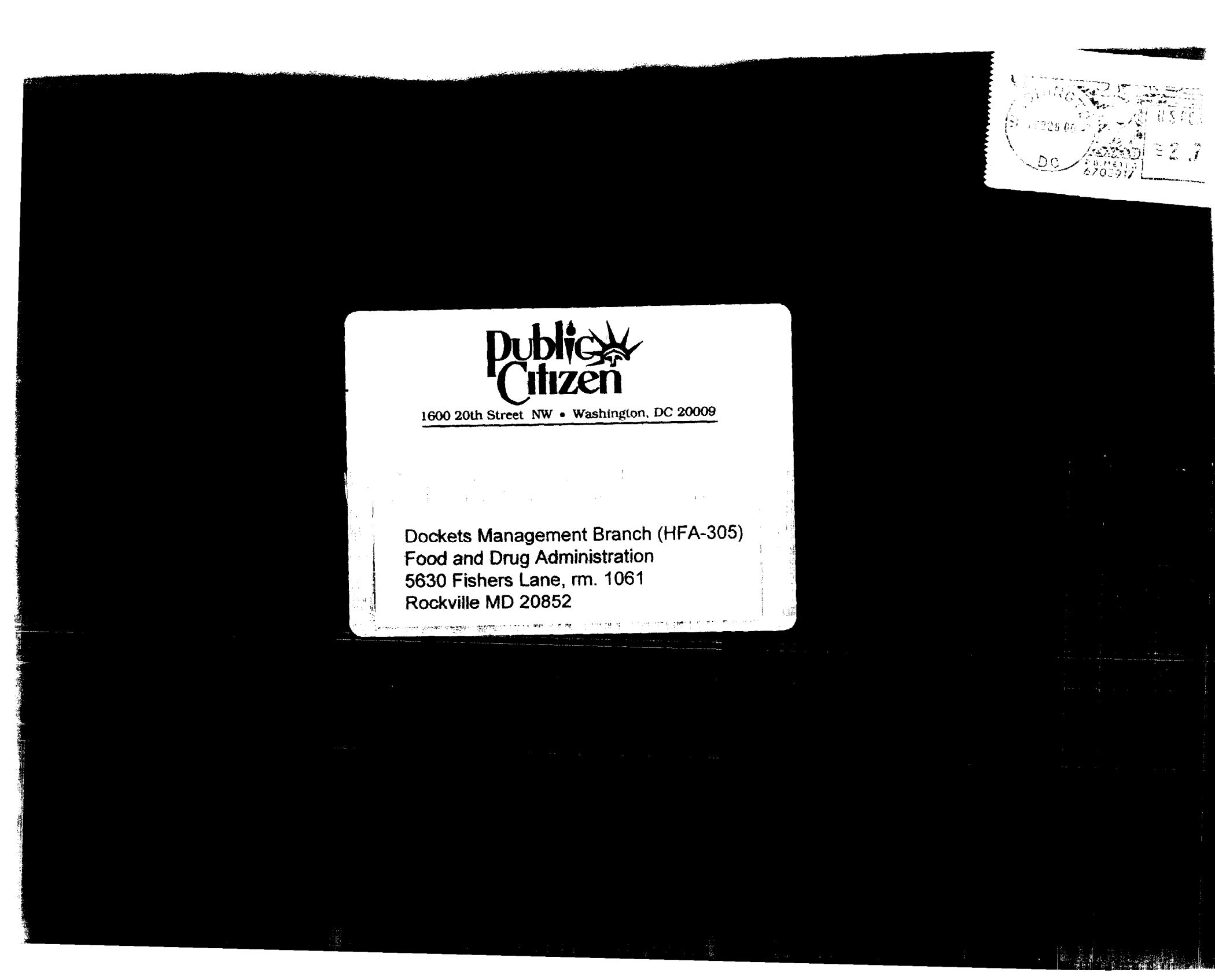
3. The health care professional's information addresses both medicine and the patient's specific health needs.		
4. The health care professional can provide and answer questions about the information in the professional labeling.		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